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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,117	02/27/2002	David W. Morris	PP23697.0001/20366-005001	7176

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EXAMINER	
AEDER, SEAN E	
ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/085,117	MORRIS ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,26,27,29 and 37-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,26,27,29 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 8/26/09 in response to the Office Action of 2/26/09 are acknowledged and have been entered.

Claims 24, 26, 27, 29, and 37-39 are pending and are currently under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons stated in the Office Action of 7/8/08, for the reasons stated in the Office Action of 2/26/09, and for the reasons set-forth below.

Claim 38 is rejected as indefinite for reciting "highly" stringent hybridization conditions, as the specification does not distinctly define the limitations of such conditions. For example, the specification teaches exemplary stringent conditions include hybridization at 60C in a solution with a sodium ion concentration from about 0.01 to 1.0M, pH 7.0 to 8.3 comprising formamide (page 11, in particular). However, those conditions are not *defined* by the claims and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This rejection can be obviated

by distinctly defining the conditions, ***including washing conditions***, under which highly stringent conditions are practiced.

In the Reply of 8/26/09, Applicant argues that one of skill in the art could readily determine suitable washing conditions. Applicant further cites paragraph 0055 and argues that the specification teaches appropriate washing conditions. Applicant further states that claim 38 is not indefinite in light of the particular application disclosure. Applicant further states that claim 38 is not indefinite in light of the teachings of the prior art. Applicant further states that claim 38 is not indefinite in light of claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

The arguments found in the Reply of 2/26/09 have been carefully considered, but are not deemed persuasive. It is noted that claim 38 recites that hybridization is performed at 60C in a solution with a sodium ion concentration from about 0.01 to 1.0M. However, it is the Office's position that the metes and bounds of "highly" stringent hybridization conditions are not clear without defining washing conditions of "highly" stringent hybridization conditions.

In regards to the argument that one of skill in the art could readily determine suitable washing conditions, it is unclear which washing conditions would be part of "highly" stringent hybridization conditions.

In regards to the argument that the specification teaches appropriate washing conditions and that claim 38 is not indefinite in light of the particular application disclosure, possible washing conditions disclosed in the specification are not read into

the claims and the specification does not disclose which washing conditions would be part of "highly" stringent hybridization conditions.

In regards to the arguments that one of skill could readily determine suitable washing conditions because high stringency conditions are known in the art or that claim 38 is not indefinite in light of the teachings of the prior art, the Examiner agrees that one could identify many different washing conditions by examining the prior art. However, it is unclear which washing conditions are encompassed by the recited methods involving "highly" stringent hybridization conditions.

In regards to the argument that claim 38 is not indefinite in light of claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made, one of ordinary level of skill in the pertinent art at the time the invention was made would not know which washing conditions could be part of "highly" stringent hybridization conditions. The washing conditions of "highly" stringent hybridization conditions are not *defined* by the claims and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26, 27, 29, and 37-39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons stated

in the Office Action of 7/8/0, for the reasons stated in the Office Action of 2/26/09, and for the reasons set-forth below.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims are drawn to methods wherein a decrease of at least 50% in a level of expression of nucleic acids having the nucleotide sequence set forth in SEQ ID NO:167 or the full complement thereof, any nucleic acid having at least 98% identity to SEQ ID NO:167, the full complement of any nucleic acid having at least 98% identity to SEQ ID NO:167, and any nucleic acid that hybridizes under highly stringent conditions to any nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or the

full complement thereof in a patient sample as compared to a second sample indicates the patient has colon cancer.

The specification discloses that SEQ ID NO:167 is a cancer associated (CA) nucleic acid (page 10 lines 9-12 and table 1, in particular). The specification further discloses that CA nucleic acids are nucleic acids that were identified through use of oncogenic retroviruses, whose sequences insert into the genome of lymphatic tissue resulting in carcinoma (page 3 lines 17-29 and page 7 lines 20-24, in particular). The specification further discloses that CA nucleic acids can be downregulated in carcinomas *and* discloses that CA nucleic acids can be upregulated in carcinomas (see lines 29-38 on page 7, in particular). *However*, of the hundreds of CA nucleic acids disclosed in the specification (see Table 1), the specification does not disclose which CA nucleic acids are upregulated and which are downregulated in particular carcinomas. Further, the specification lacks working examples demonstrating methods wherein a decrease of at least 50% in a level of expression of a nucleic acid (including nucleic acids comprising SEQ ID NO:167, full complements of SEQ ID NO:167, and just any nucleic acid the hybridizes under highly stringent conditions to SEQ ID NO:167 or the complete complement thereof) in a patient sample as compared to a second sample indicates the patient has colon cancer.

The level of unpredictability for using a particular expression pattern of a particular molecule to detect any disease is quite high. The state of the prior art dictates that one of skill in the art would not predict that a particular expression pattern of a particular molecule is indicative of a particular diseased state without a demonstration

that said particular diseased stated correlates with said particular expression pattern of said particular molecule. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and if validated (emphasis added) can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). Therefore, absent evidence demonstrating a particular expression pattern of a particular molecule correlating with a particular diseased state,

one of skill in the art would not predict said particular expression pattern of said particular molecule correlates with said particular diseased state without undue experimentation. Experimentation to identify such a correlation would in itself be inventive.

Since neither the specification nor the prior art provide evidence of methods wherein a decrease of at least 50% in a level of expression of nucleic acids having the nucleotide sequence set forth in SEQ ID NO:167 or the full complement thereof, any nucleic acid having at least 98% identity to SEQ ID NO:167, the full complement of any nucleic acid having at least 98% identity to SEQ ID NO:167, and any nucleic acid that hybridizes under highly stringent conditions to any nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or the full complement thereof in a patient sample as compared to a second sample indicates the patient has colon cancer, a practitioner wishing to practice the claimed invention would be required to provide extensive experimentation to demonstrate such an association. Such experimentation would in itself be inventive.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

In the Reply of 8/26/09, Applicant states that the claimed methods do not relate to hundreds of CA nucleic acids. Applicant further argues that the teachings of Tockman et al are not relevant when considering whether an invention is enabled under

35 U.S.C. 112, first paragraph because Tockman et al discusses recommended steps for brining a biomarker into clinical application and Tockman et al does not suggest that a biomarker that has not yet been validated for use in clinics is not “suitable as a biomarker in general". Applicant further statement that only because a biomarker has not been validated for clinical use to diagnose a particular disease, does not mean it is not enabled to diagnose the particular disease. Applicant further states that one of ordinary skill in the art can readily determine if expression of a nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or a nucleic acid having at least 98% identity to SEQ ID NO:167 is decreased relative to that of a control sample. Applicant further argues that one of ordinary skill in the art can readily determine if the amount of duplex formed upon contacting a polynucleotide that hybridizes under stringent conditions to a nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or full complement thereof with a patient sample is decreased relative to the amount of duplex formed by hybridization of such a polynucleotide to a control non-cancer sample. Applicant further states that one of ordinary skill in the art would appreciate that decreased expression of EGR1 mRNA can be used to facilitate diagnosis of colon cancer.

The arguments found in the Reply of 8/26/09 have been carefully been considered, but are not deemed persuasive. In regards to the statement that the claimed methods do not relate to hundreds of CA nucleic acids, the claimed methods relate to an infinite number of nucleic acids. The claimed methods relate to any nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or the full complement

thereof, any nucleic acid having at least 98% identity to SEQ ID NO:167, the full complement of any nucleic acid having at least 98% identity to SEQ ID NO:167, and any nucleic acid that hybridizes under highly stringent conditions to any nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or the full complement thereof.

In regards to the argument argues that the teachings of Tockman et al are not relevant when considering whether an invention is enabled under 35 U.S.C. 112, first paragraph, factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). Tockman is cited to address these factors, mainly the predictability factor and the state of the prior art factor. Tockman et al teaches the state of the art is such that the level of unpredictability for using a particular expression pattern of a particular molecule to detect any disease is quite high without a demonstration of said particular expression pattern correlating with said particular disease.

In regards to the argument that only because a biomarker has not been validated for clinical use to diagnose a particular disease, does not mean it is not enabled to diagnose the particular disease, reasons why the claimed invention is not enable are discussed above.

In regard to the arguments that one of ordinary skill in the art can readily determine if expression of a nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or a nucleic acid having at least 98% identity to SEQ ID NO:167 is decreased relative to that of a control sample and that one of ordinary skill in the art can readily determine if the amount of duplex formed upon contacting a polynucleotide that hybridizes under stringent conditions to a nucleic acid having the nucleotide sequence set forth in SEQ ID NO:167 or full complement thereof with a patient sample is decreased relative to the amount of duplex formed by hybridization of such a polynucleotide to a control non-cancer sample, undue experimentation would be required to perform the claimed methods with any predictability of success for the reasons stated above. The claims are not merely drawn to detecting nucleic acids or duplexes formed with nucleic acids. Rather, the claims are drawn to highly unpredictable methods of correlating specific expression patterns of large genera of nucleic acids with a particular disease state.

In regards to the statement that one of ordinary skill in the art would appreciate that decreased expression of EGR1 mRNA can be used to facilitate diagnosis of colon cancer, since neither the specification nor the prior art provide evidence of methods wherein a decrease in a level of expression of nucleic acids comprising SEQ ID

NO:167, full complements of SEQ ID NO:167, variants 98% identical to SEQ ID NO:167, full complements of variants 98% identical to SEQ ID NO:167, and just any nucleic acid that hybridizes under highly stringent conditions to SEQ ID NO:167 or the complete complement thereof in a patient sample as compared to a second sample indicates the patient has colon cancer, a practitioner wishing to practice the claimed invention would be required to provide extensive experimentation to demonstrate such an association and one of ordinary skill in the art would not appreciate that decreased expression of EGR1 mRNA can be used to facilitate diagnosis of colon cancer. Further, such experimentation would in itself be inventive.

Claims 24, 26, 27, 29, and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons stated in the Office Action of 2/26/09, and for the reasons set-forth below.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claims 24, 26, 27, 29, 37, and 39 recite methods wherein a decrease of at least 50% in the level of expression of nucleic acids comprising a sequence at least 98% identical to SEQ ID NO:167 or the full complement thereof in a patient sample relative to a control sample indicates that patient has colon cancer. Descriptions of methods wherein a decrease of at least 50% in the level of expression of nucleic acids

comprising a sequence at least 98% identical to SEQ ID NO:167 or the full complement thereof in a patient sample relative to a control sample indicates that patient has colon cancer are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

Claim 38 recites methods wherein a decrease of at least 50% in the level of expression of nucleic acids comprising a sequence that hybridizes under highly stringent conditions to SEQ ID NO: 167 or the complement thereof in a patient sample relative to a control sample indicates that patient has colon cancer. Descriptions of methods wherein a decrease of at least 50% in the level of expression of nucleic acids comprising a sequence that hybridizes under highly stringent conditions to SEQ ID NO: 167 or the complement thereof in a patient sample relative to a control sample indicates that patient has colon cancer are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

The specification discloses that SEQ ID NO:167 is a cancer associated (CA) nucleic acid (page 10 lines 9-12 and table 1, in particular). The specification further discloses that CA nucleic acids are nucleic acids that were identified through use of oncogenic retroviruses, whose sequences insert into the genome of lymphatic tissue resulting in carcinoma (page 3 lines 17-29 and page 7 lines 20-24, in particular). The specification further discloses that CA nucleic acids can be downregulated in carcinomas *and* discloses that CA nucleic acids can be upregulated in carcinomas (see

lines 29-38 on page 7, in particular). *However,* of the hundreds of CA nucleic acids disclosed in the specification (see Table 1), the specification does not disclose which CA nucleic acids are upregulated and which are downregulated in particular carcinomas. Further, the specification lacks working examples demonstrating methods wherein a decrease of at least 50% in a level of expression of a nucleic acid (including nucleic acids comprising SEQ ID NO:167, full complements of SEQ ID NO:167, and just any nucleic acid the hybridizes under highly stringent conditions to SEQ ID NO:167 or the complete complement thereof) in a patient sample as compared to a second sample indicates the patient has colon cancer. There is nothing in the specification suggesting that SEQ ID NO:167 is downregulated, and not upregulated, with colon cancer.

In the Reply of 8/26/09, Applicant states that the specification provides written description for both upregulation and downregulation of SEQ ID NO:167. Applicant further cites MPEP 2163 and states that when a disclosure describes a claimed invention in a manner that permits one skilled in the art to reasonably conclude that the inventor possessed the claimed invention the written description requirement is satisfied. Applicant further cites MPEP 2163.02 and states all that is required is "reasonable clarity". Applicant further states that it is important to be mindful of the generally inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement (inventions in "predictable" or "mature" require less showing of possession than inventions in more "unpredictable" arts). Applicant further states that the lack of a working example is not relevant to the issue of new matter.

The arguments found in the Reply of 8/26/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the specification provides written description for both upregulation and downregulation of SEQ ID NO:167, the specification does not provide a written description of the claimed method wherein downregulation of SEQ ID NO:167 is indicative of colon cancer. After reading the specification and the originally filed claims, in view of what is known in the art, one of skill in the art would not know whether SEQ ID NO:167 is downregulated or upregulated with colon cancer.

In regards to citation of MPEP 2163 and statement that when a disclosure describes a claimed invention in a manner that permits one skilled in the art to reasonably conclude that the inventor possessed the claimed invention the written description requirement is satisfied, one skilled in the art would not reasonably conclude that the inventor possessed a method of detecting colon cancer as recited in the instant claims because after reading the specification and the originally filed claims, in view of what is known in the art, one of skill in the art would not know whether the nucleic acids encompassed by the claims are downregulated or upregulated with colon cancer. Methods wherein nucleic acids encompassed by the claims are downregulated with colon cancer are not found with "reasonable clarity" in the specification in view of what is known in the art.

In regards to the argument that it is important to be mindful of the generally inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement (inventions in

"predictable" or "mature" require less showing of possession than inventions in more "unpredictable" arts), this invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology". Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001). Further, the level of unpredictability for using a particular expression pattern of a particular molecule to detect any disease is quite high. The state of the prior art dictates that one of skill in the art would not predict that a particular expression pattern of a particular molecule is indicative of a particular diseased state without a demonstration that said particular diseased stated correlates with said particular expression pattern of said particular molecule. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and if validated (emphasis added) can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with

subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). Therefore, absent evidence demonstrating a particular expression pattern of a particular molecule correlating with a particular diseased state, one of skill in the art would not predict said particular expression pattern of said particular molecule correlates with said particular diseased state without undue experimentation. Experimentation to identify such a correlation would in itself be inventive. Therefore, the instant invention requires more showing of possession than inventions from the predictable arts.

In regards to the argument that the lack of a working example is not relevant to the issue of new matter, a working example is not required to show possession. However, a working example would certainly be one way to demonstrate possession.

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642